STANDARDIZATION OF TEST METHODOLOGY:

A COMPARISON BETWEEN THREE SUTURE ANCHORS

A Thesis

by

SILPA P. JONNALAGADDA

Submitted to the Office of Graduate Studies of
Texas A&M University
in partial fulfillment of the requirements for the degree of

MASTER OF SCIENCE

May 2004

Major Subject: Biomedical Engineering

STANDARDIZATION OF TEST METHODOLOGY:

A COMPARISON BETWEEN THREE SUTURE ANCHORS

A Thesis

by

SILPA P. JONNALAGADDA

Submitted to Texas A&M University
in partial fulfillment of the requirements
for the degree of

MASTER OF SCIENCE

Approved as to style and content by:

William A. Hyman (Chair of Committee)	Donald A. Hulse (Member)
Hsin-I Wu (Member)	William A. Hyman (Head of Department)

May 2004

Major Subject: Biomedical Engineering

ABSTRACT

Standardization of Test Methodology: A Comparison Between Three Suture Anchors.

(May 2004)

Silpa P. Jonnalagadda, B.E., Osmania University, India

Chair of Advisory Committee: Dr. William A. Hyman

Suture anchors have been used successfully in many applications in orthopedics. They have been in the forefront of research in the recent years. Most of the studies, though, have focused on human suture anchors. This research concentrates on the veterinary aspect of suture anchors.

Currently, there is no standardization of testing methods. One of the objectives of this research is to develop a standardized method of testing that is clinically relevant, at least for veterinary use. Another objective of this research is to compare the durability of three commercial suture anchors manufactured by Innovative Animal Products, Securos Veterinary Orthopedic Inc. and IMEX™ by comparing their pullout loads after cyclic loading. This research also aims to determine whether suture anchor failure due to eyelet cut-out or suture wear-out resulting from the sharp edges of the eyelet is the major cause of failure of bone-suture anchor-bone complexes.

Cyclic loading of suture anchors during testing for durability has not been used previously even though such loading plays an important role in determining the stability of the bone-suture anchor-bone construct. The response of the construct to this type of testing followed by pullout tests has been explored in this research.

ACKNOWLEDGEMENTS

I, firstly, thank The Almighty for helping me through this endeavor. I thank my parents and my brother, Mr. Raghav Sandeep Jonnalagadda, for their unconditional support during the most difficult periods during the completion of this thesis. I thank my fiancé, Mr. Sreedhar Juttu, for believing in me and helping me believe in myself. I thank Dr. William Hyman for giving me a chance to prove myself, for being my mentor and for giving me direction in this research. I thank Dr. Donald Hulse for his expert guidance throughout the project. I thank the Testing, Machining and Repair Facility staff for the help they extended for the testing required for the research. I thank Mr. Pravin Peddiraju for his support and timely assistance in the use of different tools during the writing of this thesis. I thank Mr. Manoranjan Majji for his aid during the writing of this thesis.

TABLE OF CONTENTS

Page

ABSTRACT iii

ACKNOWLEDGEMENTS iv

TABLE OF CONTENTS v

LIST OF TABLES vi

INTRODUCTION 1

PRIOR RESEARCH 4

OBJECTIVES 8

METHODOLOGY 10

Design Specifications of Anchors 10
Methodology 11

RESULTS 15

Pullout Tests 15
Cyclic Loading Tests 18

DISCUSSION 19

Innovative Animal Products-A Comparison between Pullout Tests and Cyclic Loading Followed by Pullout Tests 19
Innovative Animal Products, Securos Veterinary Orthopedics Inc., IMEX™- A Comparison 20
Securos Veterinary Orthopedics Inc 21

CONCLUSIONS 23

REFERENCES 25

APPENDIX A 27

APPENDIX B 32

VITA 45

LIST OF TABLES

TABLE Page

1. Innovative Animal Products- Pullout Loads (In lbf) (No Cyclic Loading) 16

2. Innovative Animal Products-Pullout Loads (In lbf) (Cyclic Loading Followed by Pullout Tests) 16

3. IMEX^{TM}- Pullout Loads (In lbf) (Cyclic Loading Followed by Pullout Tests) 17

4. Securos Veterinary Orthopedics Inc. - Pullout Loads (In lbf) (Cyclic Loading Followed by Pullout Tests) 17

5. Comparison of Cyclic Loading Test Results 18

INTRODUCTION

Suture anchors are metal screws with eyelets at the head that are inserted into bone to facilitate reattachment of soft tissue. They are also used to reconstruct damaged tendons or ligaments. Suture is passed through the eyes of the anchors and secured either to soft tissue or to another anchor to hold the construct in place. Suture anchors often have self-tapping ends which enables the anchor to be screwed into place without first tapping the hole. Suture anchors have become popular in recent years because of their ease of placement. Simplified procedures can now be performed instead of major surgeries due to the convenience of the use of suture anchors placed arthroscopically to repair damaged cartilage, ligaments or tendons.

Suture anchors have many advantages over other types of repair. They have proven to reduce risk of infection and nail dystrophy in flexor digitorum tendon to bone repair and have been reported to offer more comfort to patients as compared to transcutaneous devices[1] in humans. They have also been used in glenohumeral instability[2], rotator cuff repairs[3] and in various other applications in human orthopedic surgery.[4-6] The use of suture anchors has not been limited to orthopedics. They have also been used by Hom *et al.*[7] in a pubovaginal sling procedure with reported excellent results.

The journal used as a model for this thesis is: *Arthroscopy: The Journal of Arthroscopic & Related Surgery.*

Most of the research on suture anchors is oriented towards human applications. The current research, however, deals with the use of suture anchors in veterinary medicine, specifically suture anchors used in restoration of the function of the knee joint in dogs. Currently three major companies are involved in designing and marketing screw type suture anchors for veterinary use: Securos Veterinary Orthopedics Inc., Charlton, MA (Securos), IMEX^{TM} Veterinary, Inc., Longview, TX (IMEX) and Innovative Animal Products, Rochester, MN (Innovative). The suture anchors from Innovative have cortical threads and this makes them different from the ones from Securos and IMEX. All of these anchors are intended for use to support extra-capsular reconstruction of the anterior cruciate ligament (ACL) deficient knee joint in dogs.

The pullout strength, the strength with which the anchor holds onto the bone, is extremely important in the performance of a suture anchor. If the pullout strength of a suture anchor is not higher than the maximum load it is supposed to bear, there could be failure of the bone-suture anchor-bone interface.

The direction of the load on the suture anchor plays an important role as the in-line force on the anchor would be less if the load is at an angle to the axis of the suture anchor than for a load along the axis of the suture anchor. Of course, the force parallel to bone increases in turn and this tangential force can also challenge the integrity of the bone-anchor surface by applying a complex state of loading as the anchor applies compressive and shear loads to the surrounding bone. In particular, the anchor can cause crushing of the underlying bone as it is pulled laterally. Another important feature in the design of the suture anchor is the size, shape and chamfering of the eyelet of the anchor. If the eyelet is too thin, the suture will break through the eyelet of the anchor. If the edges of the eyelet are not chamfered to a smooth enough finish, the suture will wear-out across the sharp edges of the eyelets and eventually break leading to the failure of the anchoring, even though the anchor itself may remain in place.

PRIOR RESEARCH

Means of securing soft tissue or bone to bone has been the focus of research for quite some time now, but suture anchors are a recent development. There have been many studies, at the outset, concerning the feasibility of suture anchors and lately, the durability of suture anchors. Most of the studies, though, have focused on human suture anchors, and have used porcine or other bones for testing.

Evaluating pullout strengths of suture anchors plays an important role in determining their durability. In 1995, Barber *et al.*[8] performed pullout tests on 14 suture anchors in fresh never-frozen porcine bones. The anchors were placed in three different test areas, namely, the diaphyseal cortex, metaphyseal cortex and cancellous bone troughs. The suture anchors were threaded with steel sutures to minimize failure due to suture breakage. Load was applied along the axis of the anchor at a displacement rate of 12.5 mm/sec till anchor failure. They concluded that the larger the drill-size for a screw type anchor, the higher the failure strengths. However, for non-screw type anchors, a larger drill size meant lower mean failure strengths. In 1996, similar pullout tests were performed on 8 new suture anchors. [9] They reported that for screw anchors, the mean failure strengths in all three test areas increased with the increase in the minor diameter of the screw. For non-screw anchors, the larger drill holes resulted in lower mean failure strengths in cancellous bone. In 1997, Barber *et al.*[10] performed pullout tests on biodegradable anchors and concluded that the main mode of failure for screw-type biodegradable anchors was eyelet cut-out but the main mode of failure for the non-screw-type anchors was anchor pullout. The move to "mini" anchors was supported as all the anchors were stronger than the suture they were designed for. In 1999, Barber and Herbert[11] conducted more pullout tests on both screw type and non-screw type anchors and reported that, though the new screw type anchors had higher mean failure strengths than the non-screw suture anchors, the differences between the mean failure strengths of the newer screw type and non-screw type anchors was less apparent. They also stated that the newer biodegradable anchors were comparable in mean failure strengths to the other anchors in their class. In 2003, [4] they published results using more recent types of suture anchors using a similar protocol. It was concluded that screw-type anchors had higher load to failure values as compared to the non-screw type anchors. Biodegradable anchors had lower failure loads than the non-biodegradable ones. They also concluded that all the anchors tested were stronger than the suture material used.

Cluett *et al.* [6] used fresh frozen cadaver fingers to evaluate the pullout strength of Mitec Micro Arc anchors used in the reconstruction of central slip avulsions at the proximal inter-phalangeal joint of the finger in an *in vitro* biomechanical study. They used forty pairs of fresh frozen cadaver fingers that were randomly categorized into treatment groups and control groups. Suture anchors were the method of repair in the treatment group, while the control group was subjected to horizontal mattress repair. Though there were no significant differences between the two groups, the mean failure load of the isolated anchor was 400% higher than the tendon-suture-anchor complex, signifying that the bone-anchor junction was not the weakest link in the system. Meyer *et al.*[12], however, reported that absorbable suture anchors are made of mechanically weak material and could be the weakest links in the soft tissue-anchor-bone complex.

Investigators have also developed various modified surgical procedures using suture anchors. Hom *et al.*[7] used suture anchors in a modified pubovaginal sling procedure where the anchors were placed in the pubic tubercle and were used to support a polypropylene mesh. They concluded that there were better results, greater technical ease, lesser morbidity and lower hospitalization period compared to the traditional pubovaginal sling procedure. Mitsionis *et al.*[5] conducted a study on a series of surgeries for the treatment of chronic injuries of the ulnar collateral ligament of the thumb using a free tendon graft and suture anchors with excellent results reported. Scheibel *et al.*[3] put suture anchors to use in a modified Mason-Allen technique for shoulder cuff repair and reported that the procedure was easy to perform and provided excellent initial fixation strength allowing durable osteofibroblastic integration of the reinserted cuff. Bonin *et al.*[2] have performed a procedure for flexorum digitorum tendon-to-bone repair using suture anchors and have concluded that suture anchors reduced risk of infection, nail dystrophy and offered better comfort to the patient. Karr *et al.*[2] used suture anchors in shoulder surgery and reported that, though suture anchors are being widely used in open and arthroscopic surgeries about the shoulder, there can be significant risks if the anchor is placed improperly or if the index procedure fails.

There has been recent research on the effect on sutures when used in suture anchors. Bardana *et al.*[13] published results in 2003 on their work on the effect of suture anchor design and orientation on suture abrasion and showed that suture durability depended on load orientation. They also reported that anchor angulation, suture anchor eyelet design and composition and suture position in the eyelet played an important role in the durability of the suture in the anchor.

Pullout tests on suture material were performed by Meyer *et al.*[14] to determine the load strength at which suture material fails with metallic suture anchor eyelets. They concluded that failure loads depend on the sharp edges of the suture anchor and that failure can occur at up to 73% below the suture material strength on a smooth hook. They also suggested that the orientation of the suture anchor played a key role in suture failure at the eyelets.

Though cyclic loading is considered important for testing the durability of suture anchors, little emphasis has been made on the topic in the literature.

OBJECTIVES

Most of the earlier work focuses on the uses of suture anchors in humans. This research concentrates on the veterinary aspect of suture anchors. These suture anchors are used in dogs with knee joints that cannot support weight due to damage to the anterior cruciate ligament. Hence, this is a new avenue of research in the field.

The simplicity of using suture anchors in procedures will be of little use if there is a high incidence of suture or anchor failure. There is reason to believe that sharp edges of eyelets can be a major cause of suture failures. Since there is limited test and performance data on the use of suture anchors, one of the main objectives of this research is to find out whether the failure of the suture anchor due to eyelet cut-out or suture wear-out resulting from the sharp edges of the eyelets could be a major cause of failure for the overall construct. This was studied by cyclic lateral loading of the suture anchors in fresh frozen dog bones. Another objective of this research is to compare the durability of three commercially available anchors by comparing their pullout strengths after cyclic loading. Also, since there have been no published reports for the tests done on the Innovative anchors, unlike the anchors from the other two companies, pullout strengths prior to and after testing were obtained for this anchor.

Currently, no standardized methodology is available for this type of testing. Therefore, an aim of this research was to develop a standard methodology for testing suture anchors that is clinically relevant, at least for veterinary use. This research aspires to promote effective product selection by delineating an effective procedure for the testing of suture anchors for use in ACL reconstruction in the veterinary field, and by reporting preliminary results for the products tested.

METHODOLOGY

Design Specifications of Anchors

The suture anchors used in this study were obtained from Innovative, IMEX and Securos. Innovative and IMEX provided sample suture anchors to be used for this testing. The Securos suture anchors were purchased directly from the company. Photographs of the suture anchors are available in Appendix A, figures 1 through 3.

All the anchors are made of 316LVM stainless steel and are specifically designed for use in dogs weighing up to 70 lbs. The anchors are nominally 3.5 mm in outside screw thread diameter. The hole in the head of the Innovative anchor has a diameter of 0.046 inches while the Securos anchor is 0.055 inches in diameter with a minimum of 0.062 inches radius on the inner edge of the hole (said to be the ideal radius to reduce stress concentrations). The radius on the outer edge of the head can be used to wrap suture around it to remove stress concentrations, although this procedure is not part of the written instructions. The hole in the Innovative Animal Products anchor is chamfered to $0.010 * 45^0$.

The design of the Securos anchor is unique in that the anchor is attached to an anchor spindle that is inserted into the pin chuck on a drill so that the anchor can be inserted into pre-drilled cortical bone using the drill. The anchor spindle or shaft is broken off at the break-off point after insertion of the anchor in the bone. The break-off point has a defined dimension to allow the anchor shaft to break off without any damage to the bone due to wobbling. Special treatment is given to the metal at that location in order to make it work properly.

The detailed dimensions for the IMEX anchors were not directly available, but they are nominally 3.5 mm in outside thread diameter.

Methodology

The canine femur and tibia were used as bone samples. The anchors were inserted in the inferior pole of the lateral fabella of the femur and the posterior wall of the long digital extensor groove in the tibia. Only the rear legs were used for the procedure. Photographs of the sites of insertion of the suture anchors are shown in Appendix A, figures 4(a) and 4(b). The bones were obtained from the Department of Small Animal Medicine and Surgery, College of Veterinary Medicine, Texas A&M University from cadavers that died from causes unrelated to this research. Thus, there was no need to sacrifice animals for this study. The bones were acquired from mixed breeds of dogs weighing approximately 40-50 lbs. Prior to being used for this study, the bones were examined by Dr. Hulse, Professor, Department of Small Animal Medicine and Surgery, College of Veterinary Medicine, Texas A&M University to ensure that they were free from any obvious damage or disease that could induce unwarranted variation into the experiment.

After harvesting, the bones were stored at -80 ^{0}C. The bones were thawed at room temperature (23 ^{0}C) for 24 hours and stripped of all soft tissue except between the tibia and the femur before testing. The bone shafts were cut in half breadth-wise using a band saw so that the bones would fit in the apparatus specially designed for this study. Holes were drilled into pre-determined sites on the bone using a 3.2 mm drill bit with a drill speed of 200 rpm for all anchors. The Innovative and IMEX suture anchors were screwed in place with the help of a screwdriver that was unique for each type of anchor. The Securos anchors, however, were screwed in with the help of the drill by placing the anchor shaft in the pin chuck. As intended in the designs, the shaft was broken off after the complete insertion of the anchor in the pre-drilled hole. After the anchors were correctly placed Ethibond No. 5 braided polyester suture was threaded through the holes of the suture anchors and tied securely. The anterior cruciate ligament was cut to imitate actual situations in which the bone anchors are used.

Two types of tests were performed on the anchors, namely, pullout tests and cyclic loading followed by pullout tests. Only cyclic loading followed by pullout tests were performed on the IMEX and the Securos anchors. Three sets of bones were used for each type of anchor. The procedure for testing for the Innovative anchors was different from the anchors from the other two companies so that we could compare the durability of the anchor before and after cyclic loading. This was done since there have been no published results pertaining to the tests done on the Innovative anchors prior to the current testing, and therefore no data was available for the durability of the anchor. For testing the Innovative anchors, both rear legs were harvested from three dogs. This yielded six bone specimens. For each dog, pullout tests without cyclic loading were performed on one set of bones, while pullout tests after cyclic loading were performed on the other set of bones. New suture anchors were used for each specimen.

The testing was done at the Testing, Machining and Repair Facility, Texas Engineering Experiment Station, Texas A&M University. A MTS (MTS Systems Corp., Minneapolis, Minnesota) servohydraulic testing machine (model 312.31S) was used for the tests. Two types of fixtures were designed specifically for the tests. For the cyclic loading tests, the bones were mounted on a device designed so that they made an angle of 140^0 with each other. The bones were restrained in order to prevent extraneous movement when load was applied on them. A load of 300N was applied to the bone ends of the joint to simulate actual conditions in the dog's knee. A dog takes an average of 18,000 steps (cycles) per day at a trot assuming two hours of activity per day[15]. The bones were subjected to a maximum of 75,000 cycles. This would roughly amount to the number of steps a dog would take in four days. This number was decided upon after taking the number of cycles required for adequate results and the time taken to complete them into consideration. The cycles were regulated by the use of software called TestStar™ (MTS Systems Corp., Minneapolis, Minnesota). The maximum number of cycles that each joint could withstand prior to failure either due to suture wear-out or eyelet cut-out was measured.

For the pullout tests, the bone was secured in two different ways depending on the configuration of the specimen. The principle behind both the methods was essentially the same. The bones were fixed in a restraining device and the anchors were pulled axially by threading stainless steel nylon coated cable (Small Parts, Inc., Miami Lakes, Florida) through the eyelets of the anchors. The specified breaking point of the cable is approximately 170 lbf. The anchors were pulled till they were completely separated from the bone. The difference between the tests was in the way the bones were restrained. In one method, the bone was clamped to a steel plate to prevent movement of the bone during pullout. In the other method, the cable was pulled through a jig specially fabricated for this test. The pullout strengths were also measured using TestStar™. Illustrations of the pullout tests, cyclic loading tests and the apparatus used during the testing are available in Appendix A, figures 5 through 7.

RESULTS

The data obtained from the experiments for cyclic loading and pullout strength is discussed below.

Pullout Tests

The data obtained from the pullout tests of the anchors without cyclic loading and after cyclic loading for Innovative anchors is given first. Pullout tests without cyclic loading were not conducted for the other anchors. The results of the pullout loading tests have been shown in Tables 1-4. The graphs for each of the pullout tests are shown in Appendix B.

Cyclic Loading Tests

The data obtained from the cyclic loading tests is shown in Table 5. The number of cycles that each complex withstood was recorded by the software used in the testing.

Table 1: Innovative Animal Products- Pullout Loads (In lbf) (No Cyclic Loading)

	Femur	**Tibia**
Specimen 1	**182.4**	**159.7**
Specimen 2	**157.8**	**176.2**
Specimen 3	**139.6**	**148.8**
Average Pullout Loads	**159.9**	**161.6**

Table 2: Innovative Animal Products- Pullout Loads (In lbf) (Cyclic Loading Followed by Pullout tests)

	Femur	**Tibia**
Specimen 1	**69.7**	**145.4**
Specimen 2	**169.5**	**173.9**
Specimen 3	**129.9**	**64.2**
Average Pullout Loads	**123.0**	**127.8**

Table 3: IMEX™- Pullout Loads (In lbf) (Cyclic Loading Followed by Pullout tests)

	Femur	**Tibia**
Specimen 1	**105.3**	**134.6**
Specimen 2	**150.7**	**69.7**
Specimen 3	**153.2**	**128.8**
Average Pullout Loads	**136.4**	**111.0**

Table 4: Securos Veterinary Orthopedics Inc.- Pullout Loads (In lbf) (Cyclic Loading Followed by Pullout tests)

	Femur	**Tibia**
Specimen 1	**92.2**	**135.5**
Specimen 2	**79.2**	**27.5**
Specimen 3	**131.9**	**71.4**
Average Pullout Loads	**101.1**	**78.1**

Table 5: Comparison of Cyclic Loading Test Results

	Innovative Animal Products	**Securos Veterinary Orthopedics Inc.**	**IMEX^{TM}**
Specimen 1	**15,872**	**5,928**	**75,000**
Specimen 2	**75,000**	**75,000**	**75,000**
Specimen 3	**27,401**	**75,000**	**75,000**
Average Number of Cycles	**39,424**	**51,976**	**75,000**

DISCUSSION

Innovative Animal Products-A Comparison between Pullout Tests and Cyclic Loading Followed by Pullout Tests

The loads obtained from pullout tests without and after cyclic loading were averaged. The mean load for the pullout tests without cyclic loading for the femur was 159.9 lbf and was 161.6 lbf for the tibia (as shown in Table 1). The mean pullout loads after cyclic loading were 123.0 lbf and 127.8 lbf for the femur and the tibia respectively (as shown in Table 2). The pullout loads were higher in the tibia. This was more obvious in the pullout tests without cyclic loading. The pullout loads were greater in the tests without cyclic loading than in the tests done after cyclic loading. This agrees with the hypothesis that pullout loads would be lower after cyclic loading as a result of damage to the bone. The average differences between the loads in the femur and tibia were 36.9 lbf and 33.8 lbf respectively. But, the pullout loads in each category were high enough to be considered clinically safe even though one of the pullout loads in the tibia and femur in the tests after cyclic loading registered low values. These bones were not from the same animal. This was because all the other values were well into the safe range; as were the average pullout loads in each category. Hence, though the difference between the pullout loads in tests without cyclic loading and after cyclic loading is large, the suture anchors are considered clinically safe in this aspect after 75,000 cycles. Additional testing is required to determine the rate of loss of strength, and whether additional cycles would further degrade the integrity of the bone-anchor interface.

Innovative Animal Products, Securos Veterinary Orthopedics Inc., IMEX™- A Comparison

During the third test involving cyclic loading of the Securos anchors, it was observed immediately after starting the test that the suture between the anchors was loose. The test was resumed after re-tying the suture securely.

The results from the pullout tests after cyclic loading for each product were compared. The average pullout loads for the Innovative anchors were 123.0 lbf and 127.8 lbf in the femur and the tibia respectively as reported earlier. The average pullout loads for the Securos anchor was 101.1 lbf in the femur and 78.1 lbf in the tibia (as shown in table 4) while the IMEX anchor measured average pullout loads of 136.4 lbf and 111.0 lbf in the femur and the tibia respectively (as shown in Table-3). The IMEX anchor shows a better pullout load in the femur as compared to the anchors from the other two companies, while the Innovative anchor shows a higher pullout load in the tibia. The pullout loads in the IMEX and Innovative anchors are similar and show consistently higher values compared to the Securos anchor. The average pullout load obtained from the Securos anchor for the tibia is too low to be in the clinically safe range. This may be due to the design of the screw threads or the insertion method. Also, though acceptable, the pullout loads for the femur are less than the values obtained from the other two products.

In the cyclic loading tests, all the suture anchors failed due to suture wear-out. There was no incidence of anchor failure due to eyelet fracture. In fact, no obvious damage to any part of the anchor or bone was found upon examination of the anchor after the pullout tests. The average number of cycles that the sutures in the Innovative anchor withstood was 39,424 while the average for the Securos was 51,976 cycles. None of the sutures attached to the IMEX anchors failed at the 75,000 cycle limit. The Innovative anchor performed the poorest in this category. This could have been because of the type of chamfering of the eyelet edge.

Two of the Innovative anchor-suture-anchor complexes failed before the 75,000 cycle limit was completed. Only one of the Securos Veterinary Orthopedics Inc. complexes failed while none of the IMEX™ complexes failed. Even though all the IMEX™ complexes lasted 75,000 cycles, there was evidence of considerable suture wear-out in all of them. This was evident in all the Innovative anchors also. This obvious wear suggests that suture failure would occur at a higher number of cycles.

Securos Veterinary Orthopedics Inc.

As mentioned earlier, only one of the Securos complexes failed due to suture failure while both the other Securos anchors lasted the designated 75,000 cycle limit. Furthermore, the failure occurred with only 5,928 cycles before failure. This was considered unusual because there was minimal suture wear-out visible in the complexes that survived for the full 75,000 cycles. This could have been a result of a defective anchor, improper placement of the anchor or pre-damaged suture.

It was noticed that the complex that failed had higher pullout loads than the complexes that survived the entire experiment. This was particularly evident in the tibia. The pullout load in the former complex was 135.5 lbf while the average pullout load in the latter complex was 49.5 lbf. This difference is too large to be overlooked. Also, the pullout loads for the complexes that lasted the entire protocol did not fall in the safe load range. These results suggest that at a higher number of cycles, there is a significant decrease in the pullout loads.

CONCLUSIONS

One of the objectives of this study was to determine whether eyelet cut-out or suture wear-out resulting from the edges of the eyelets could be a major cause of failure for a bone-suture anchor- bone construct. It was determined that there was no occurrence of anchor failure due to eyelet cut-out and that suture wear-out was the major cause of the failure of the complex.

It was also one of the aims of this study to compare the suture anchors from the three companies and determine the positive and negative aspects of their designs. Upon comparison of the pullout loads of anchors from the three companies, it was concluded that the anchors from Innovative Animal Products and IMEX™ had the best pullout strengths, and that these were large enough to be clinically acceptable. The Securos Veterinary Orthopedics Inc. anchors had the lowest pullout strengths. But, there was maximum suture wear in the IMEX™ and Innovative Animal Products anchors. Even though all the IMEX™ anchors withstood the entire 75,000 cycles, it was apparent from the condition of the suture that they would fail if the tests were continued. This was concluded to be because of the nature of the chamfering of the eyelet edges. Hence, it was concluded that Innovative Animal Products and IMEX™ should modify the design of their anchor to provide a smoother suture bearing surface. The Securos Veterinary Orthopedics Inc. should modify the design of their anchor to have higher pullout loads.

An effort has been made to delineate a standardized protocol for the testing of suture anchors for veterinary use through this research. It is proposed that for all further testing on suture anchors, pullout tests before and after cyclic testing be compared. Also, most of the previously reported testing focuses on pullout tests. The importance of cyclic lateral loading has been shown with respect to both the Securos Veterinary Orthopedics Inc. and Innovative Animal Products anchors. Hence, it is also proposed that cyclic lateral loading be incorporated into the testing protocol for suture anchors.

REFERENCES

1. Bonin N, Obert L, Jeunet L, Garbuio P, Tropet Y. Flexor Digitorum tendon-to-bone repair using a suture anchor: A prospective study using early active motion. *Chirugie de la Main* 2003; 22:305-311.
2. Kaar TK, Schenck, RC Jr., Wirth MA, Rockwood CA Jr.. Complications of metallic suture anchors in shoulder surgery: A report of 8 cases. *Arthroscopy* 2001; 17:31-37.
3. Schiebel MT, Habermeyer P. A modified Mason-Allen technique for rotator cuff repair using suture anchors. *Arthroscopy* 2003; 19:330-333.
4. Barber FA, Herbert MA, Richards DP. Sutures and suture anchors- Update 2003. *Arthroscopy* 2003; 19:985-990.
5. Mitsionis GI, Varitimidis SE, Sotereanos G. Treatment of chronic injuries of the ulnar collateral ligament of the thumb using a free tendon graft and bone suture anchors. *J Hand Surg* 2000; 25:208-211.
6. Cluett J, Milne AD, Yang D, Morris SF, Repair of central slip avulsions using Mitek Micro Arc bone anchors. *J Hand Surg [Am]* 1999; 24:679-682.
7. Hom D, Desautel MG, Lumerman JH, Feraren RE, Badlani GH. Pubovaginal sling using polypropylene mesh and vesica bone anchors. *Urology* 1998; 51:708-713.
8. Barber FA, Herbert MA, Click JN. The ultimate strength of suture anchors. *Arthroscopy* 1995; 11:21-28.
9. Barber FA, Herbert MA, Click JN. Internal fixation strength of suture anchors-

Update 1997. *Arthroscopy* 1997; 13:355-365.

10. Barber FA, Herbert MA, Click JN. Suture anchor strength revisited. *Arthroscopy* 1996; 12:32-38.
11. Barber FA, Herbert MA. Suture Anchors- Update 1999. *Arthroscopy* 1999; 15:719-725.
12. Meyer DC, Fucentese SF, Ruffieux K, Jacob HAC and Gerber C. Mechanical testing of absorbable suture anchors. *Arthroscopy* 2003; 19:188-193.
13. Bardana DD, Burks RT, West JR, Greis PE. The effect of suture anchor design and orientation on suture abrasion: An *in vitro* study. *Arthroscopy* 2003; 19: 274-281.
14. Meyer DC, Nyffeler RW, Fucentese SF, Gerber C. Failure of suture material at suture anchor eyelets. *Arthroscopy* 2002; 18:1013-1019.
15. Hulse A, Ferry K, Fawcett A, Gentry D, Hyman W, Geller S, Slater M. Effect of intermedullary pin size on reducing bone plate strain. *Vet Comp Orthop Traumatol* 2000; 13:185-190.

APPENDIX A

Figure 1 - Innovative Animal Products Anchor

Figure 2 - IMEX^{TM} Anchor

Figure 3 (a) - Securos Veterinary Orthopedics Anchor (Anchor without drill shaft)

The above figure was obtained from www.securos.com.

Figure 3 (b) - Securos Veterinary Orthopedics Anchor (Anchor showing break-away shaft design)

Figure 4(a) - Site of Insertion of Suture Anchor (Femur)

Figure 4(b) – Site of Insertion of Suture Anchor (Tibia)

The apparatus shown in the figure was used in of the methods in pullout testing.

Figure 5 - Apparatus Used in Testing (MTS Servohydraulic Testing Machine)

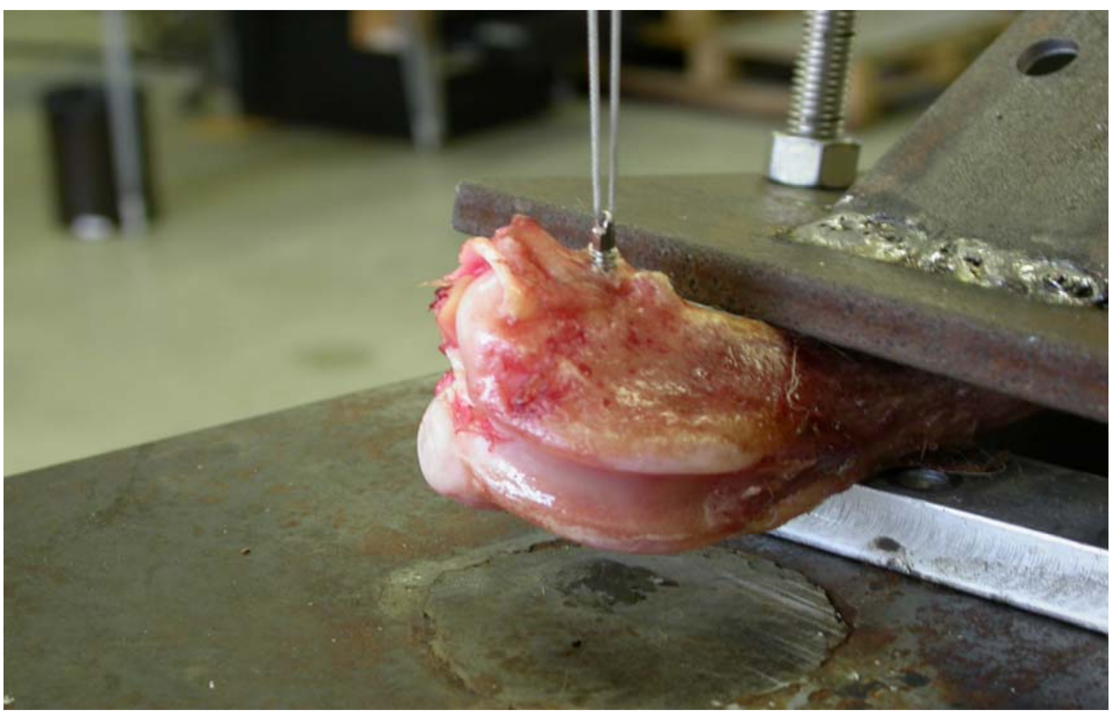


Figure 6 - One of the Methods of Pullout Testing

Figure 7 - Apparatus Used in Cyclic Loading Tests

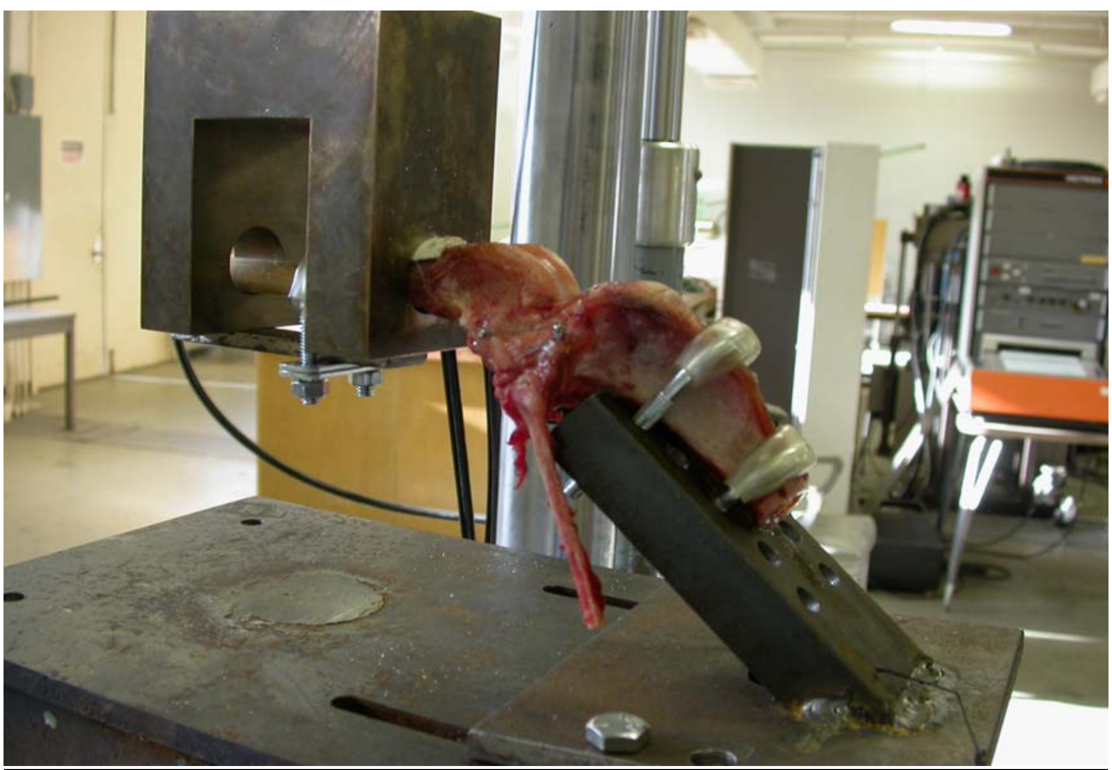
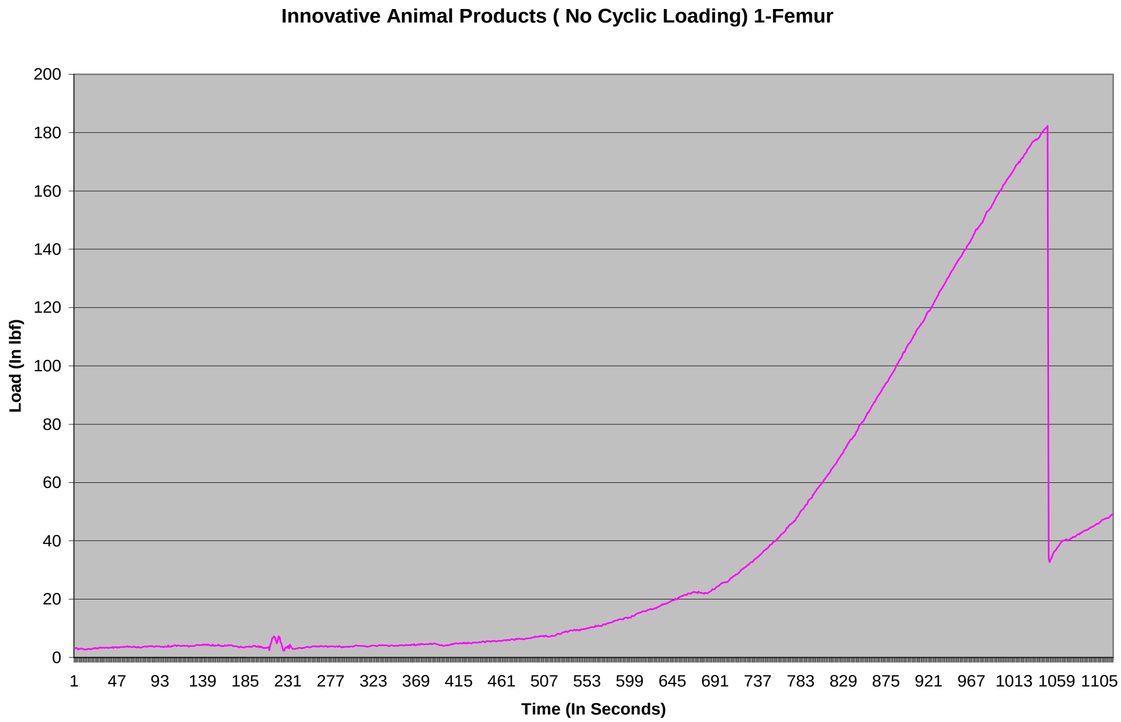


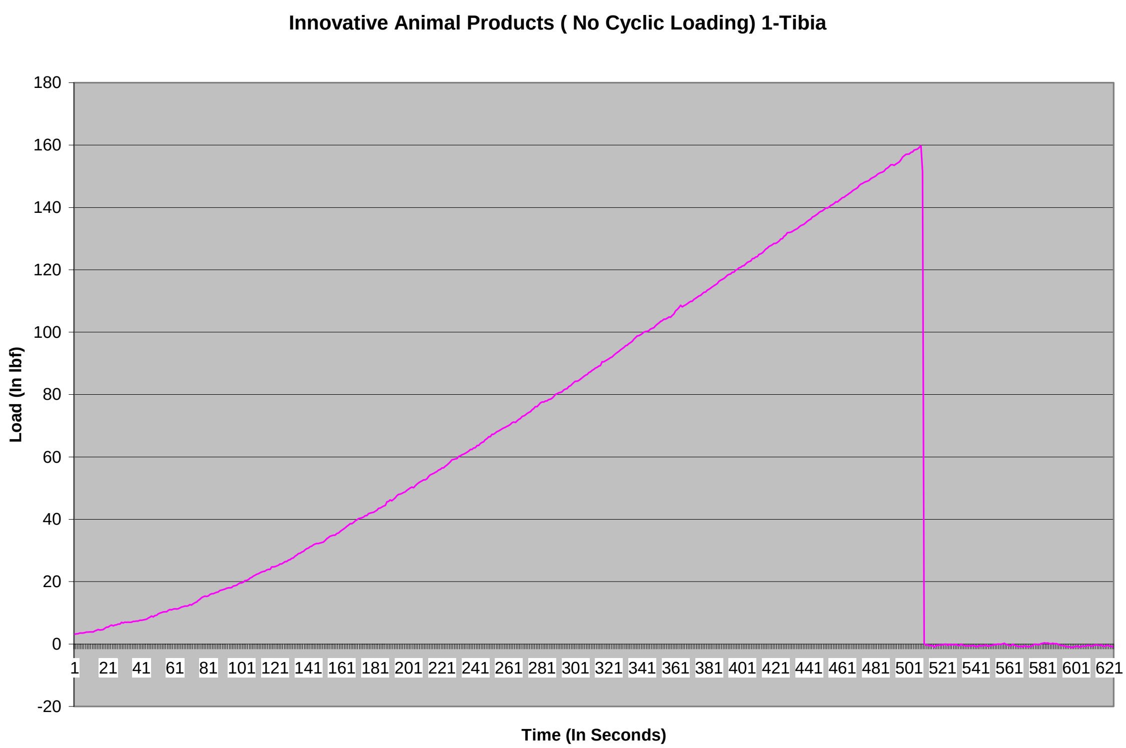
Figure 8 - Cyclic Loading Testing

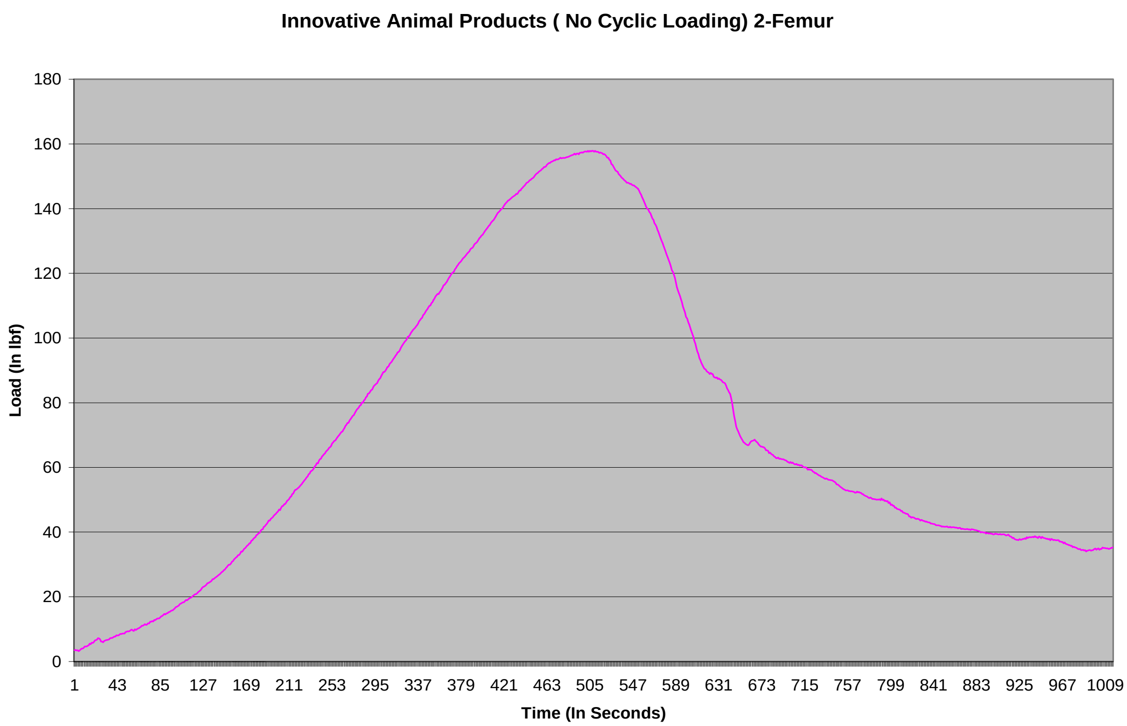
APPENDIX B

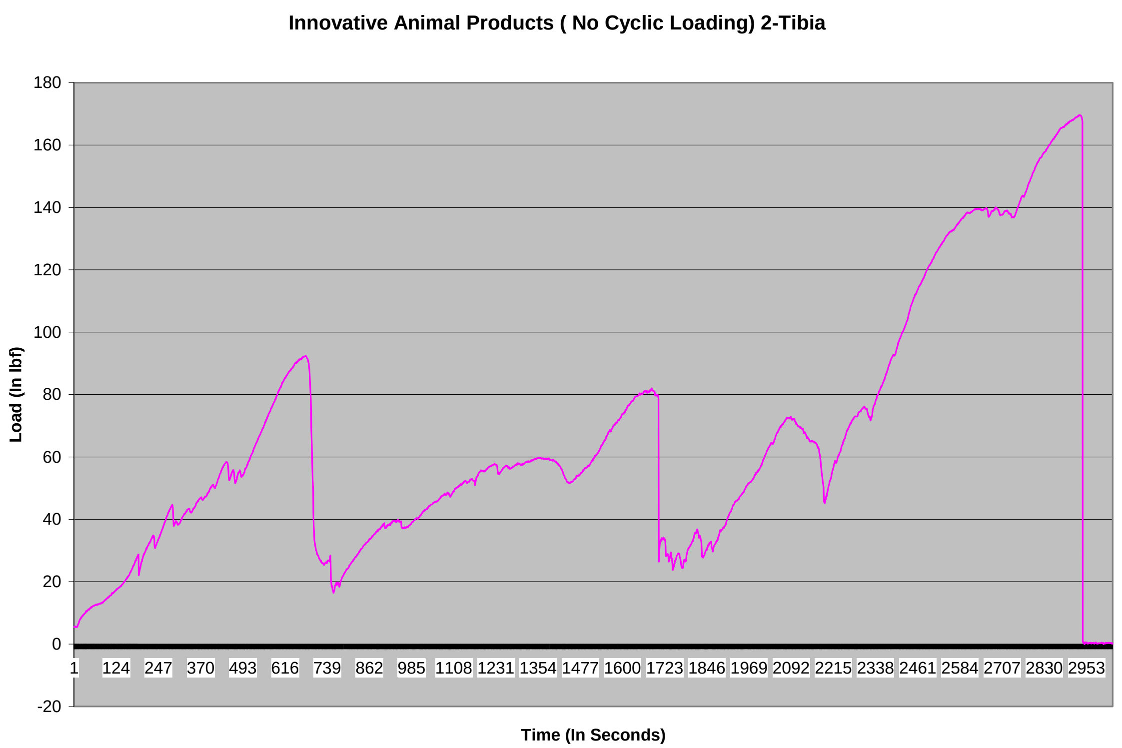
The pullout loads from the pullout tests were obtained using the software TestStar^{TM}. The graphs indicating the peaks loads are shown in this section. The pullout loads have been plotted with respect to time.

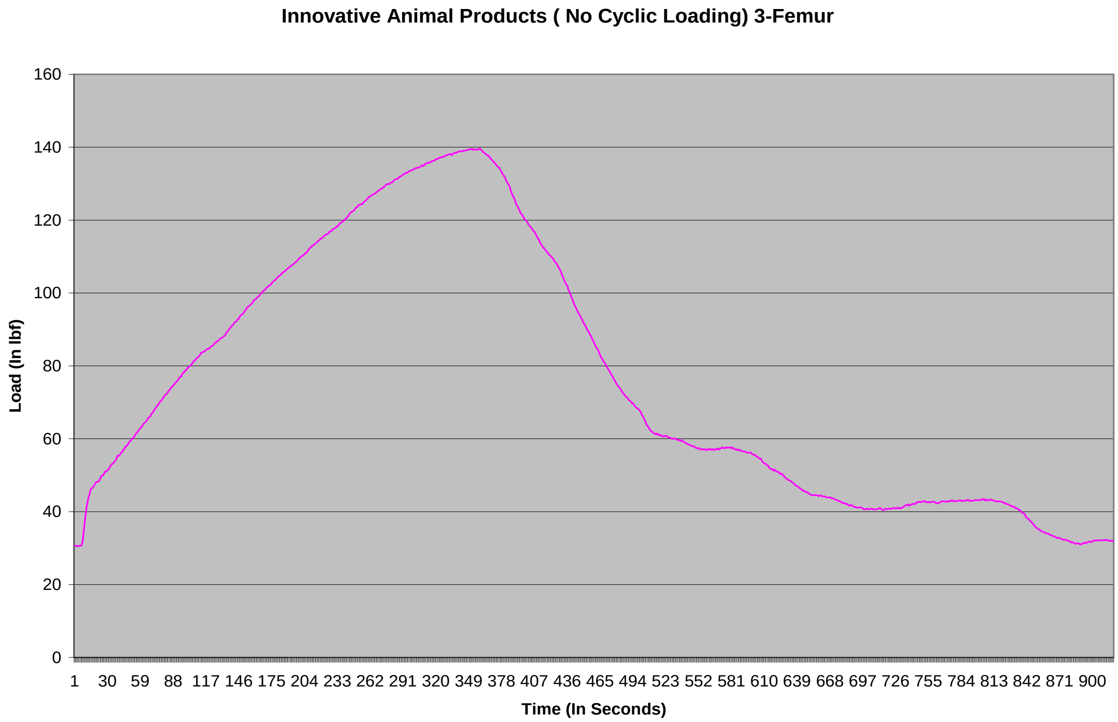
Innovative Animal Products (No Cyclic Loading)



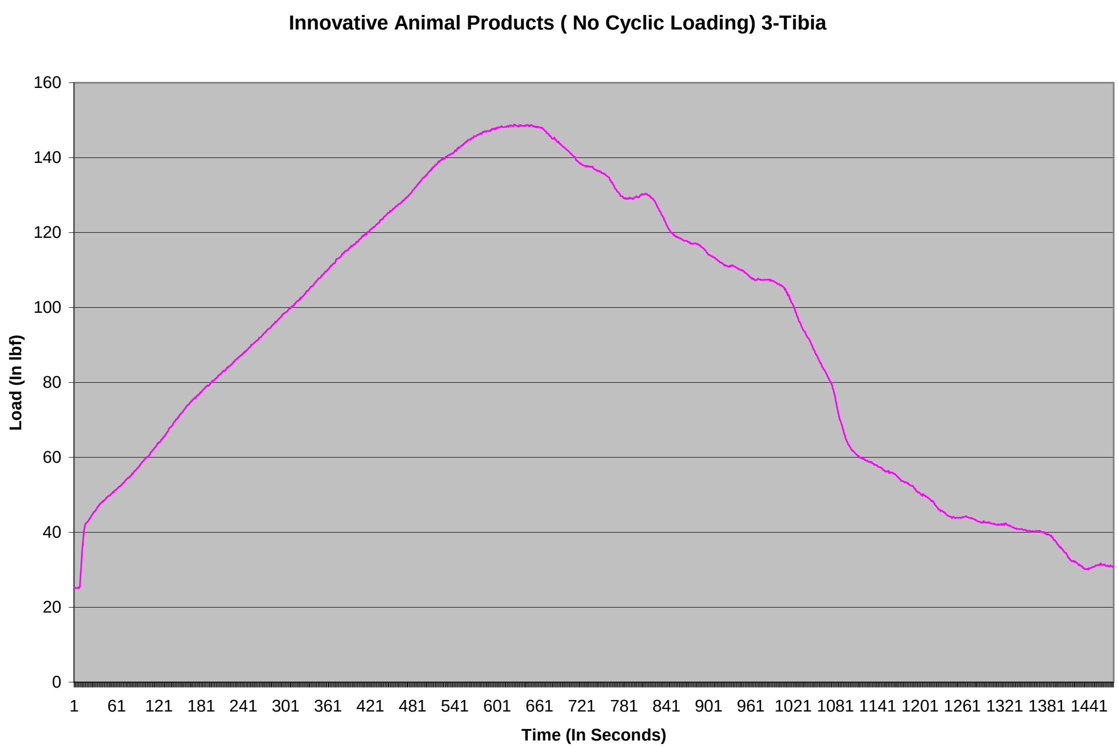



Innovative Animal Products (No Cyclic Loading) 2-Femur
Load (In lbf)
180
160
140
120
100
80
60
40
20
0
1 43 85 127 169 211 253 295 337 379 421 463 505 547 589 631 673 715 757 799 841 883 925 967 1009
Time (In Seconds)


Innovative Animal Products (No Cyclic Loading) 2-Tibia
Load (In lbf)
180
160
140
120
100
80
60
40
20
0
-20
1 124 247 370 493 616 739 862 985 1108 1231 1354 1477 1600 1723 1846 1969 2092 2215 2338 2461 2584 2707 2830 2953
Time (In Seconds)

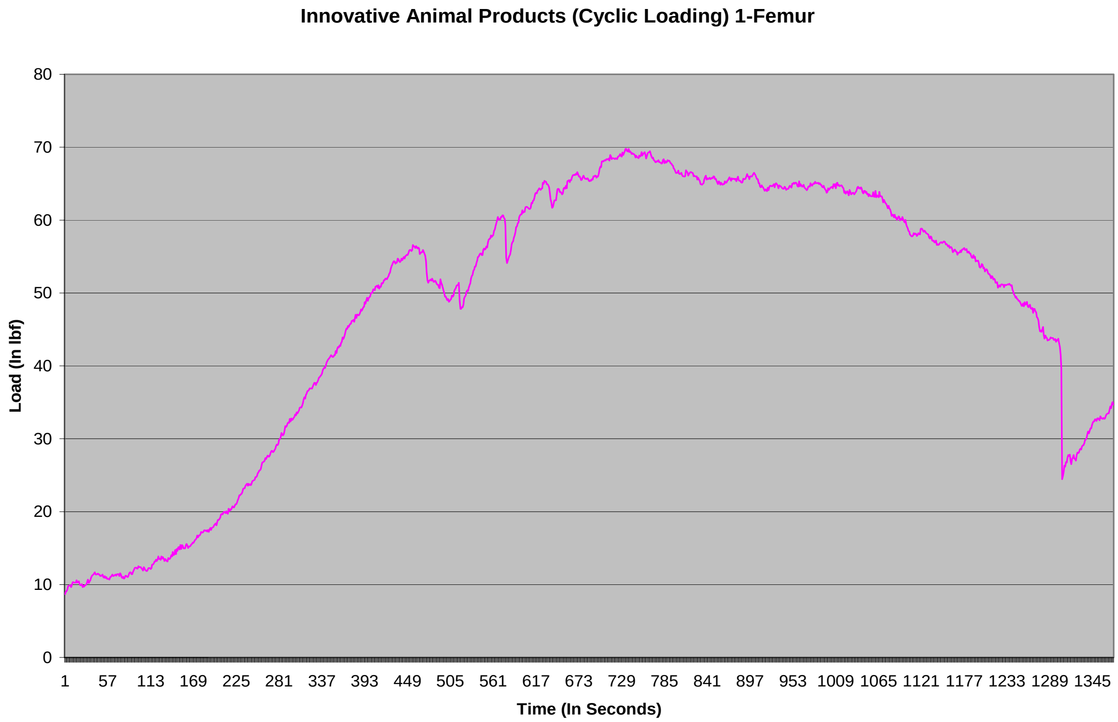


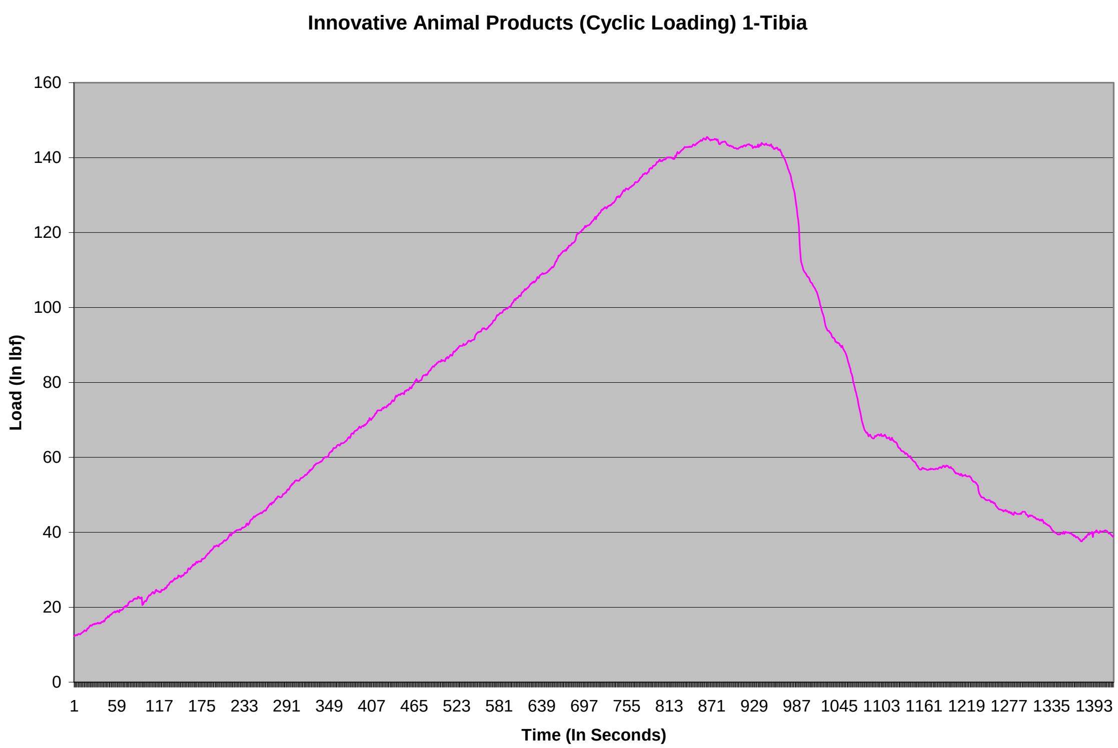
Innovative Animal Products (No Cyclic Loading) 3-Femur
Load (In lbf)
0
20
40
60
80
100
120
140
160
1 30 59 88 117 146 175 204 233 262 291 320 349 378 407 436 465 494 523 552 581 610 639 668 697 726 755 784 813 842 871 900
Time (In Seconds)

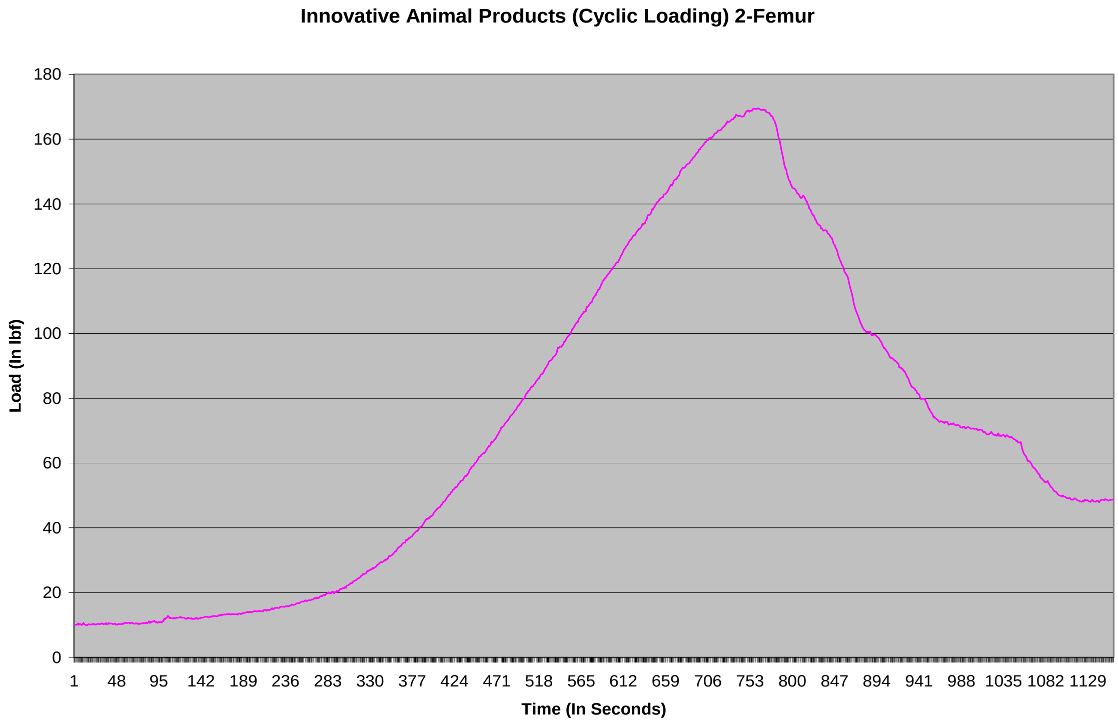


Innovative Animal Products (No Cyclic Loading) 3-Tibia
Load (In lbf)
0
20
40
60
80
100
120
140
160
1 61 121 181 241 301 361 421 481 541 601 661 721 781 841 901 961 1021 1081 1141 1201 1261 1321 1381 1441
Time (In Seconds)

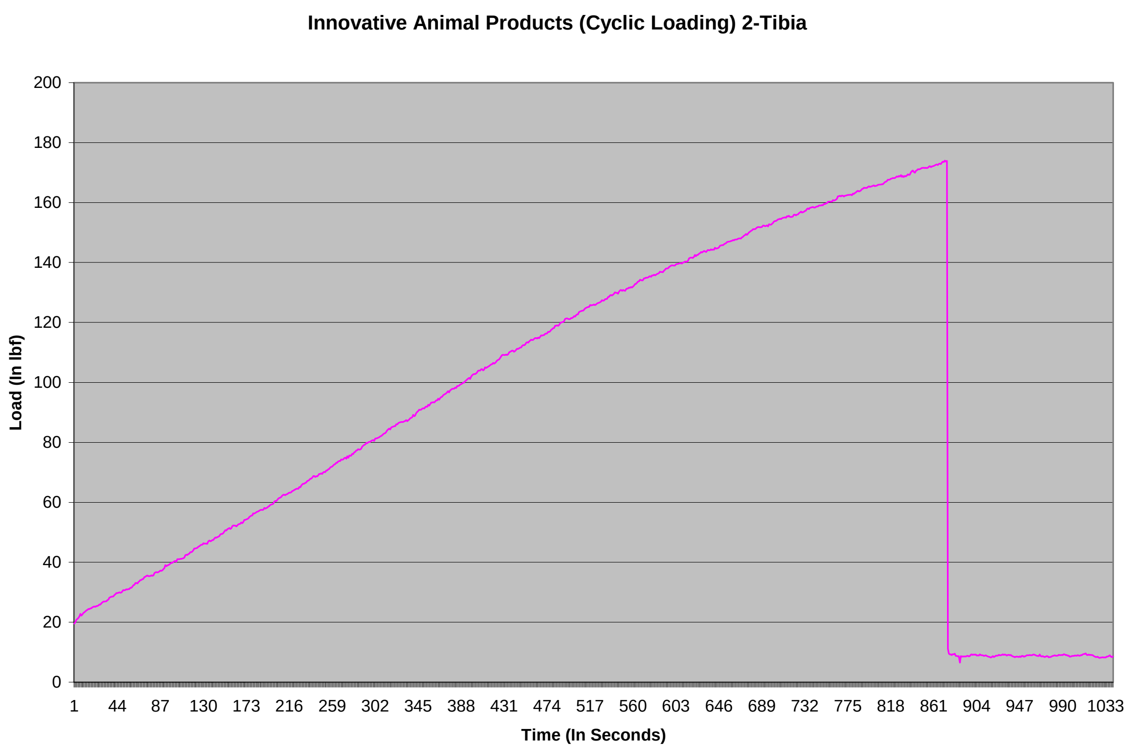
Innovative Animal Products (Cyclic Loading)



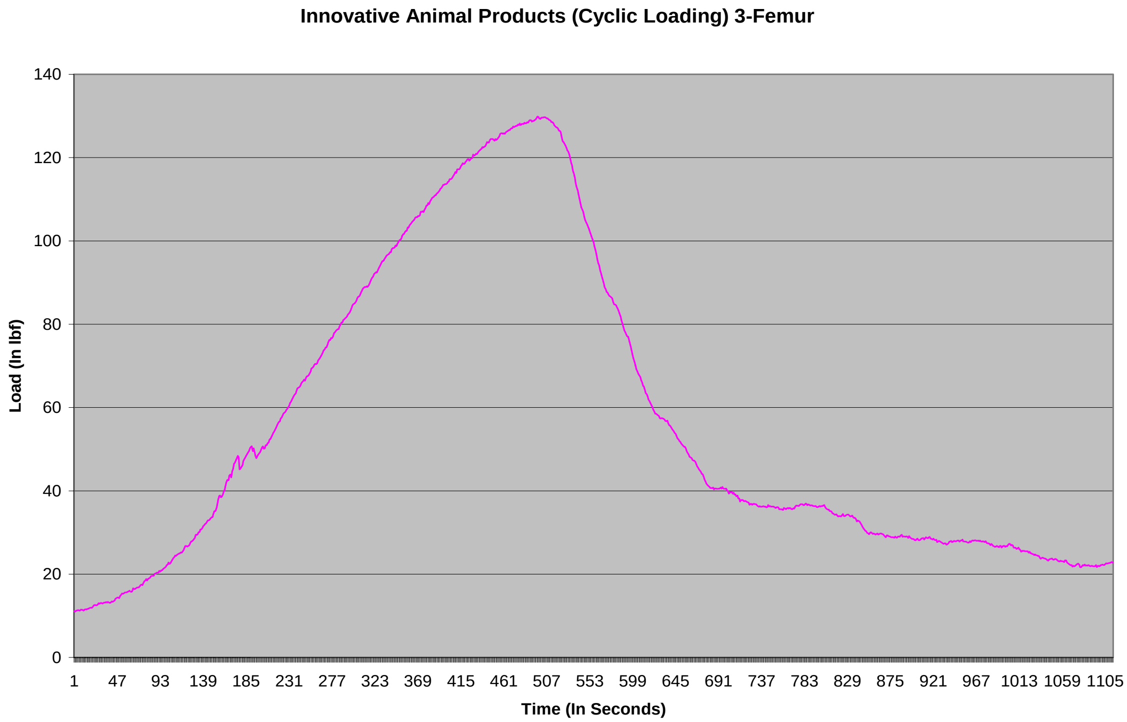


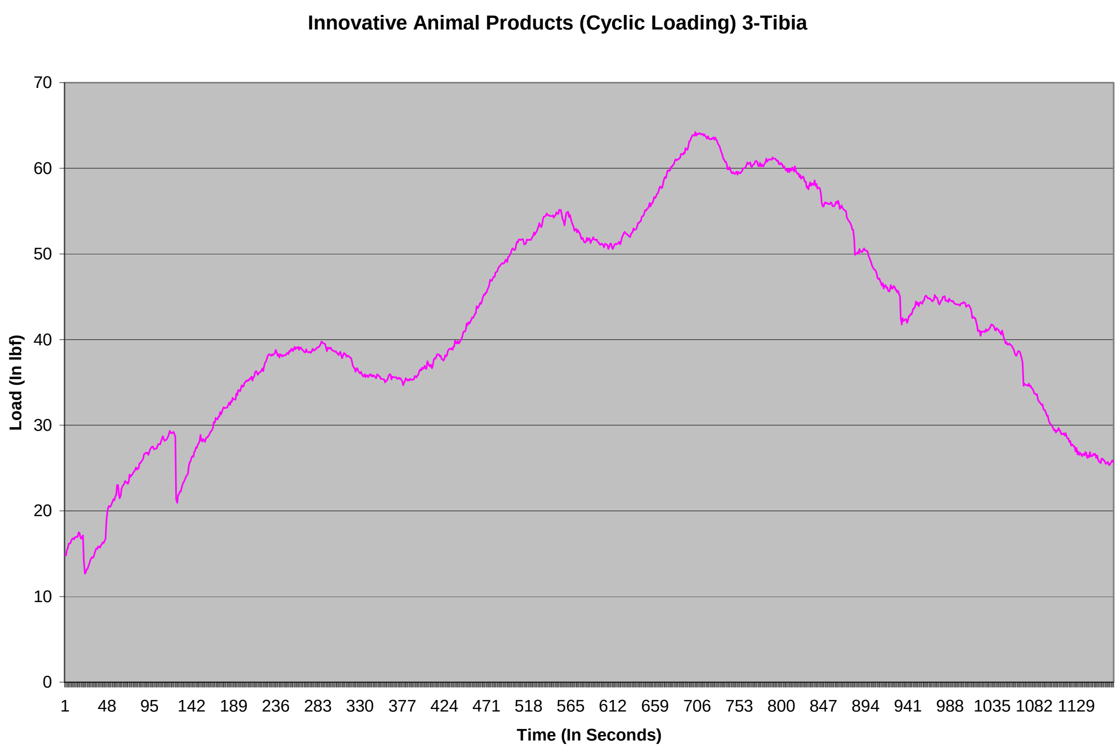


Innovative Animal Products (Cyclic Loading) 2-Femur
Load (In lbf)
0
20
40
60
80
100
120
140
160
180
1 48 95 142 189 236 283 330 377 424 471 518 565 612 659 706 753 800 847 894 941 988 1035 1082 1129
Time (In Seconds)

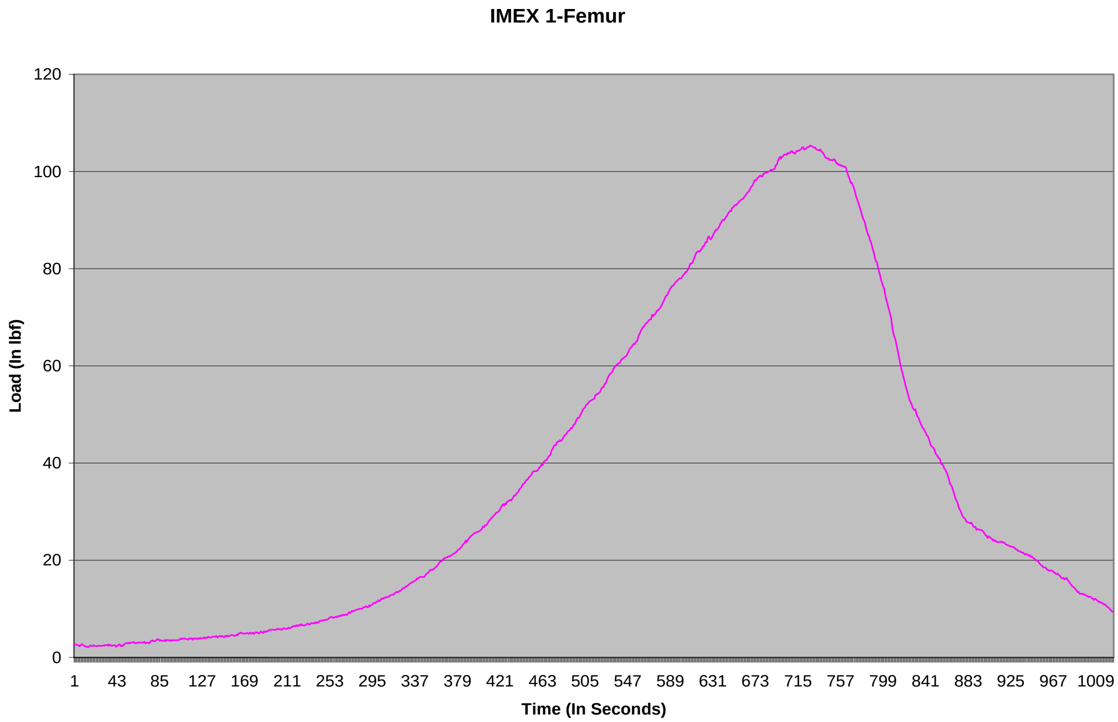


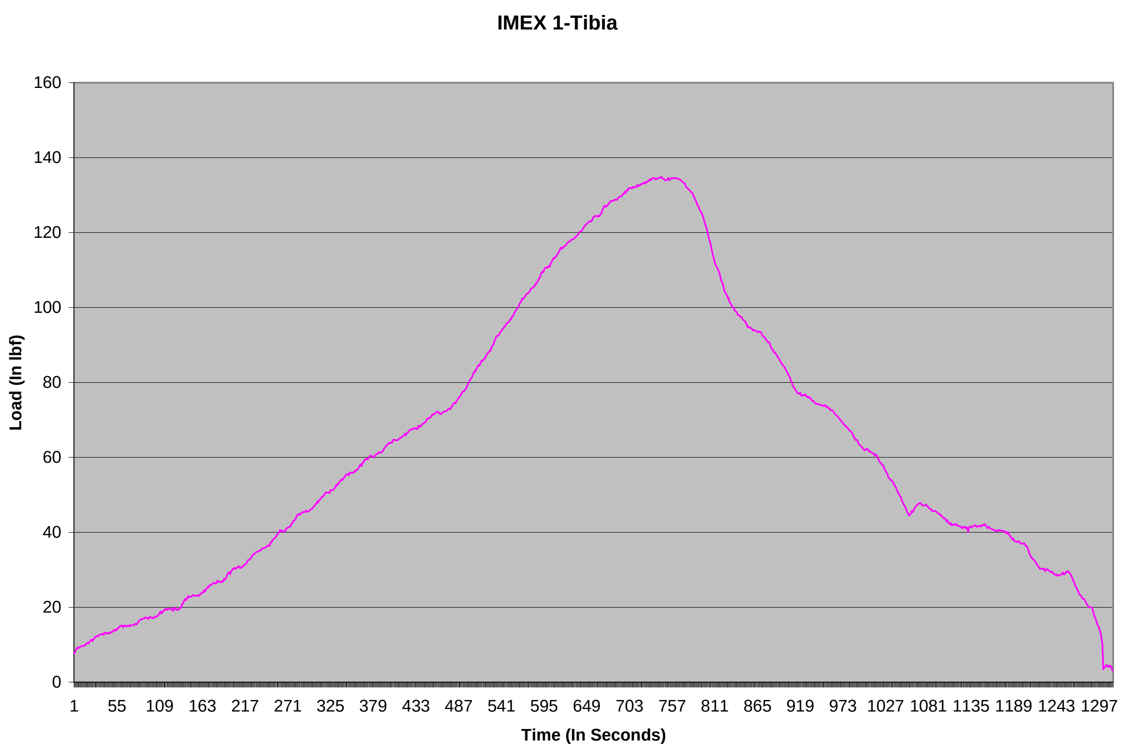
Innovative Animal Products (Cyclic Loading) 2-Tibia
Load (In lbf)
0
20
40
60
80
100
120
140
160
180
200
1 44 87 130 173 216 259 302 345 388 431 474 517 560 603 646 689 732 775 818 861 904 947 990 1033
Time (In Seconds)


Innovative Animal Products (Cyclic Loading) 3-Femur
140
120
100
80
60
40
20
0
Load (In lbf)
1 47 93 139 185 231 277 323 369 415 461 507 553 599 645 691 737 783 829 875 921 967 1013 1059 1105
Time (In Seconds)

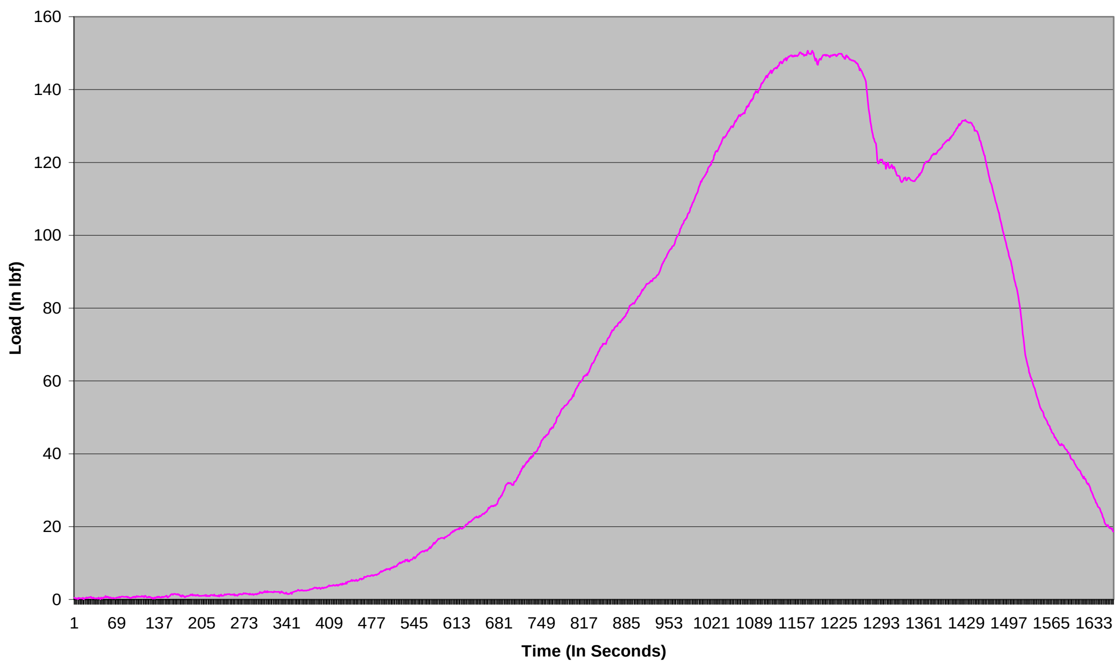

Innovative Animal Products (Cyclic Loading) 3-Tibia
70
60
50
40
30
20
10
0
Load (In lbf)
1 48 95 142 189 236 283 330 377 424 471 518 565 612 659 706 753 800 847 894 941 988 1035 1082 1129
Time (In Seconds)

IMEX[TM]

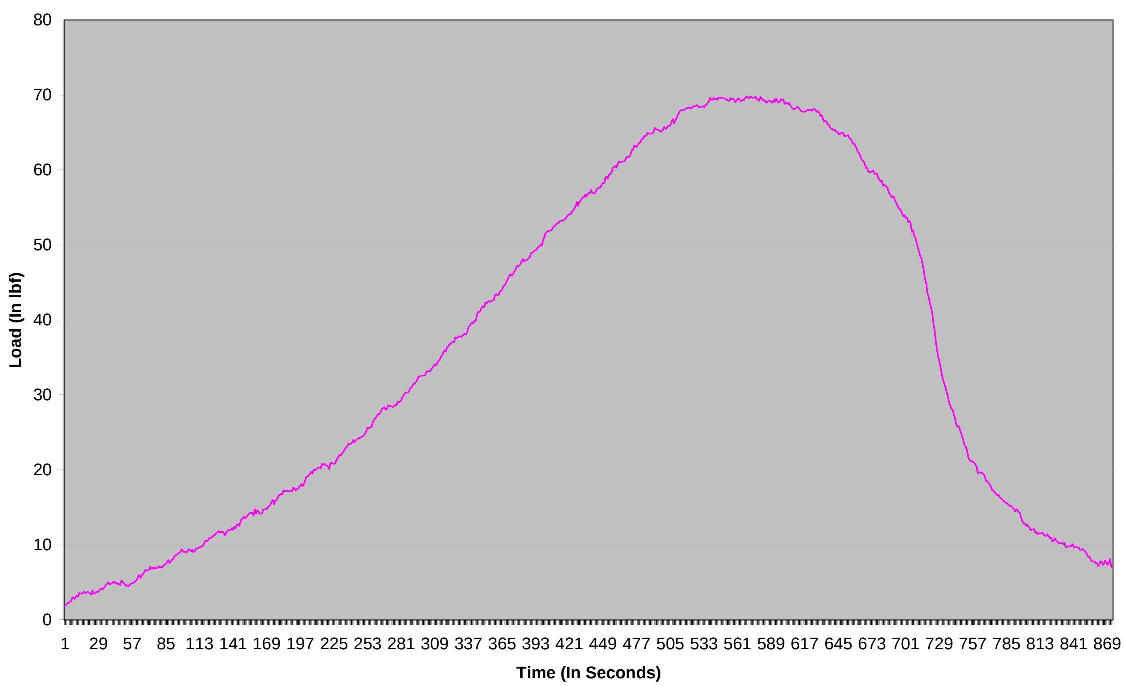

IMEX 1-Femur
Load (In lbf)
Time (In Seconds)
120
100
80
60
40
20
0
1 43 85 127 169 211 253 295 337 379 421 463 505 547 589 631 673 715 757 799 841 883 925 967 1009

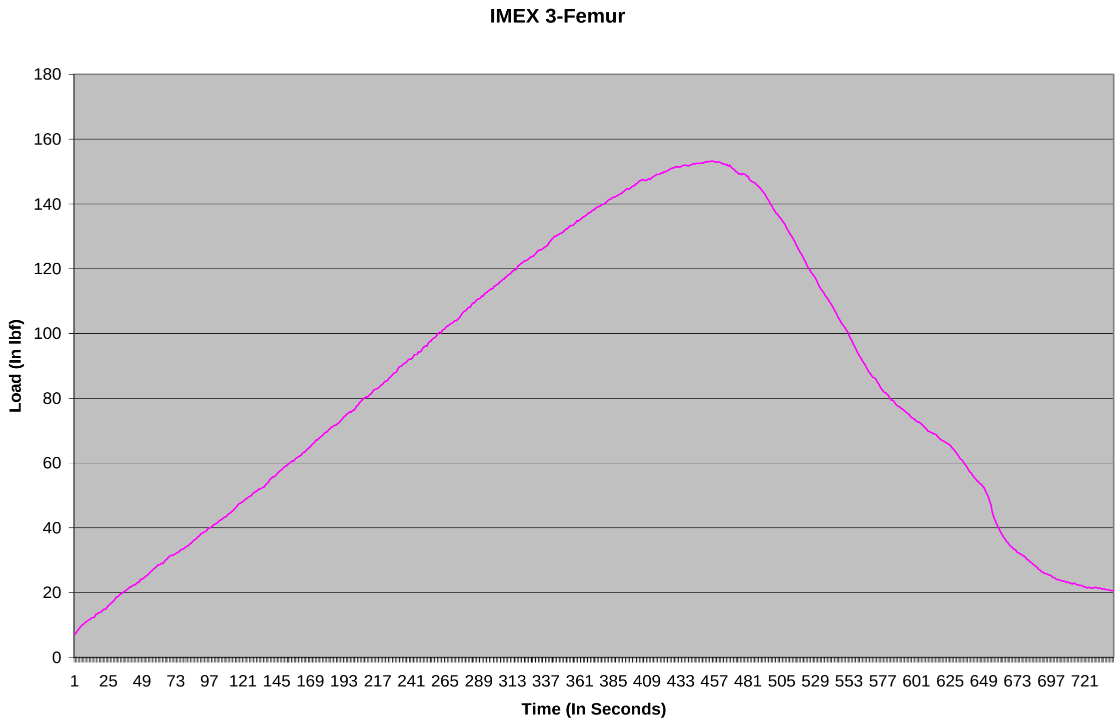

IMEX 1-Tibia
Load (In lbf)
Time (In Seconds)
160
140
120
100
80
60
40
20
0
1 55 109 163 217 271 325 379 433 487 541 595 649 703 757 811 865 919 973 1027 1081 1135 1189 1243 1297

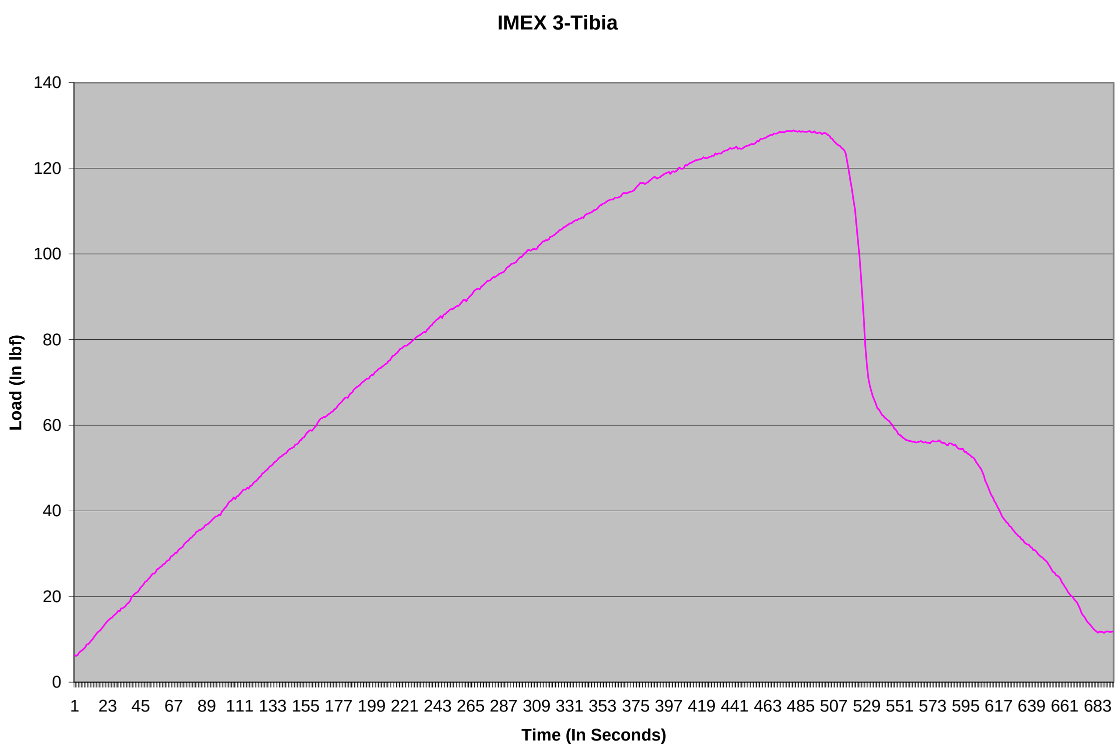
IMEX 2-Femur



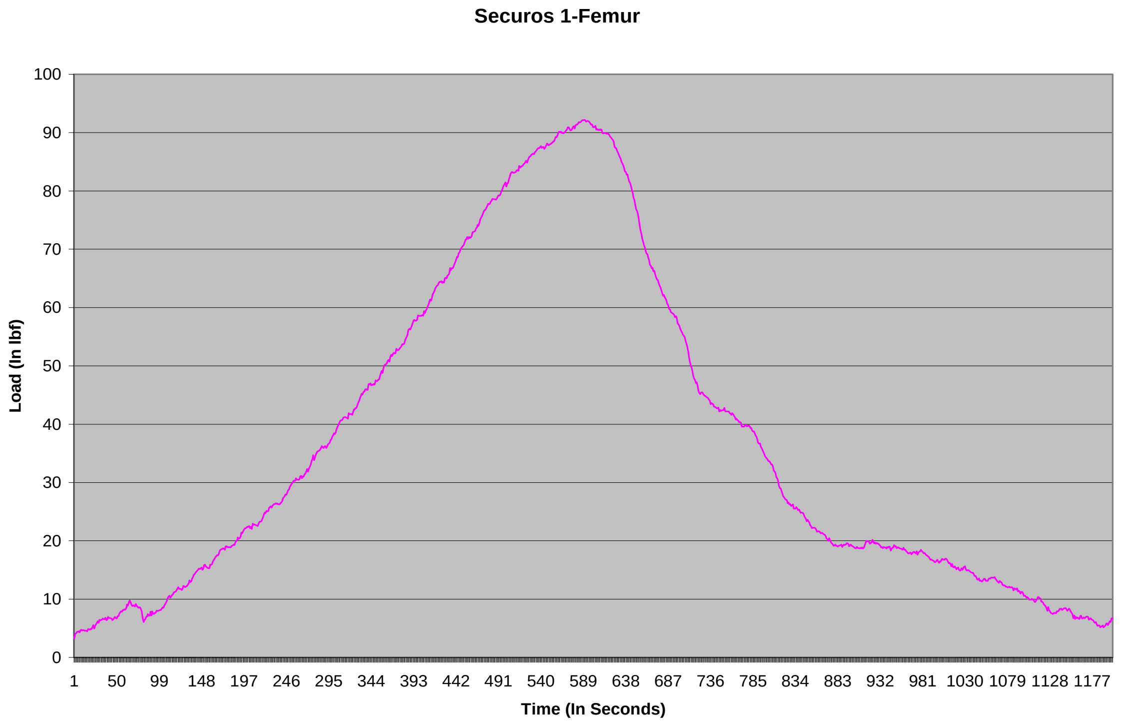
IMEX 2-Tibia

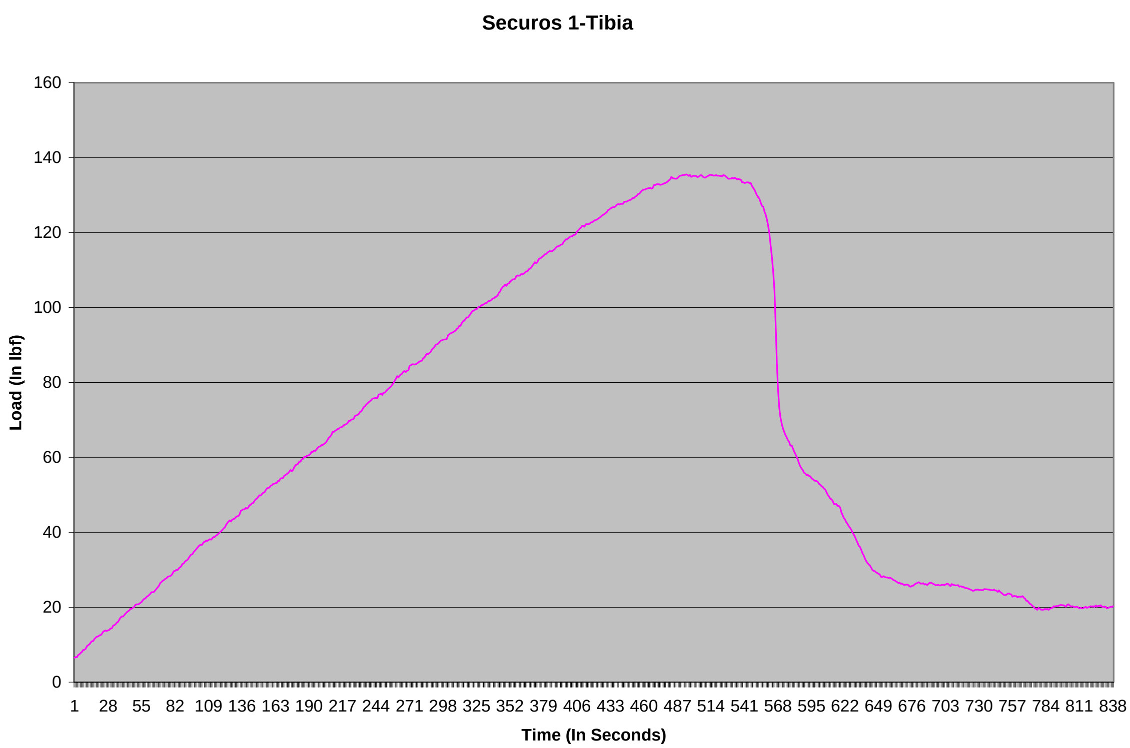


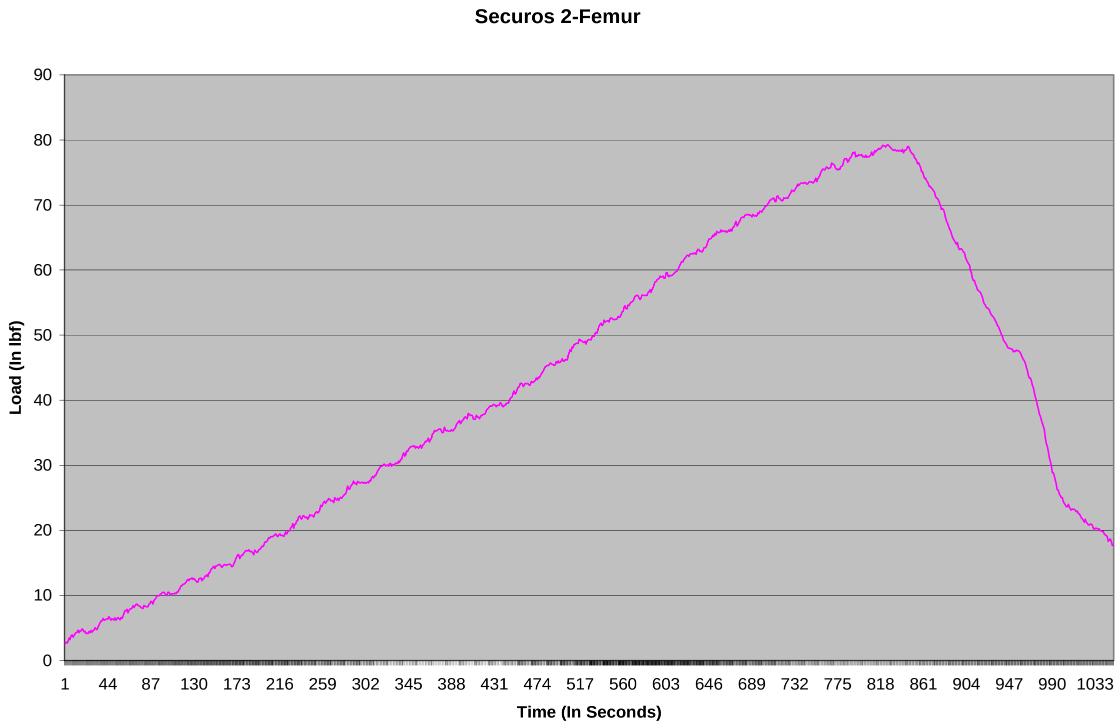

IMEX 3-Femur
Load (In lbf)
0
20
40
60
80
100
120
140
160
180
1 25 49 73 97 121 145 169 193 217 241 265 289 313 337 361 385 409 433 457 481 505 529 553 577 601 625 649 673 697 721
Time (In Seconds)

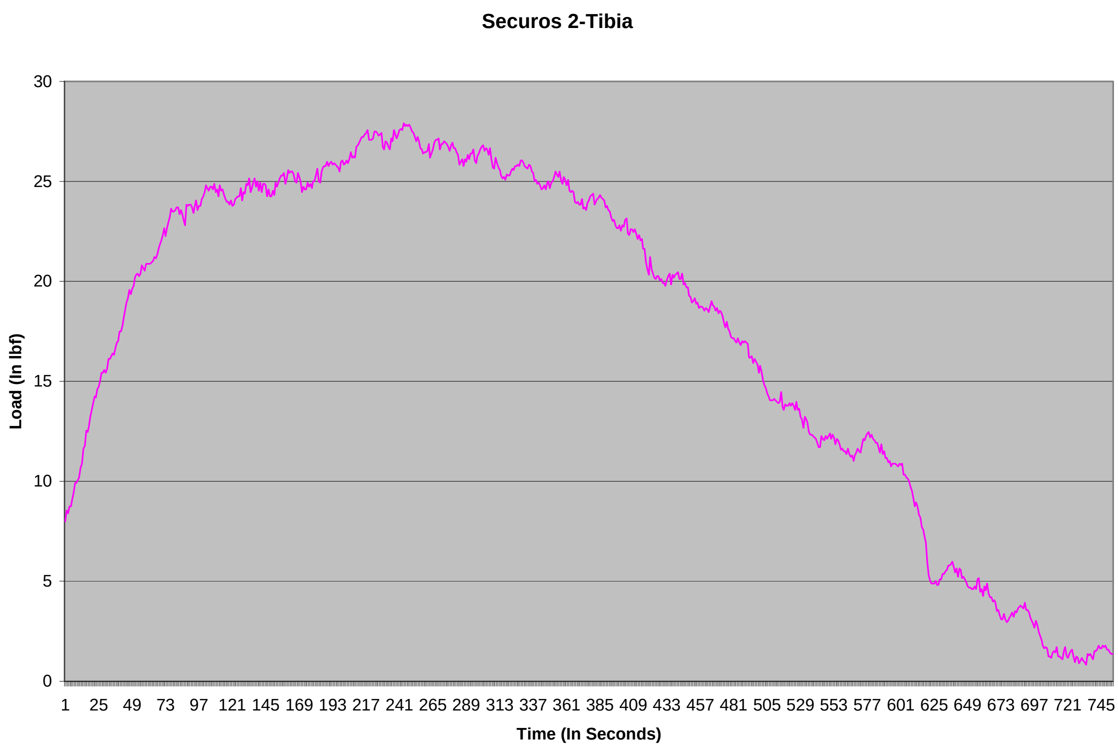

IMEX 3-Tibia
Load (In lbf)
0
20
40
60
80
100
120
140
1 23 45 67 89 111 133 155 177 199 221 243 265 287 309 331 353 375 397 419 441 463 485 507 529 551 573 595 617 639 661 683
Time (In Seconds)

Securos Veterinary Orthopedics Inc.

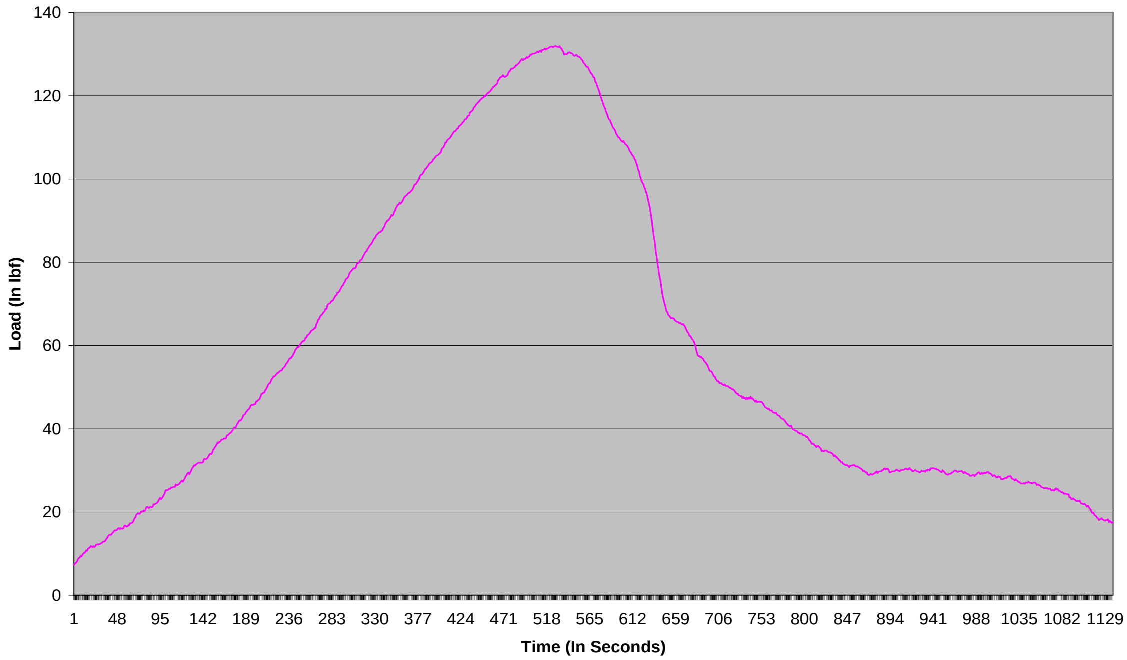




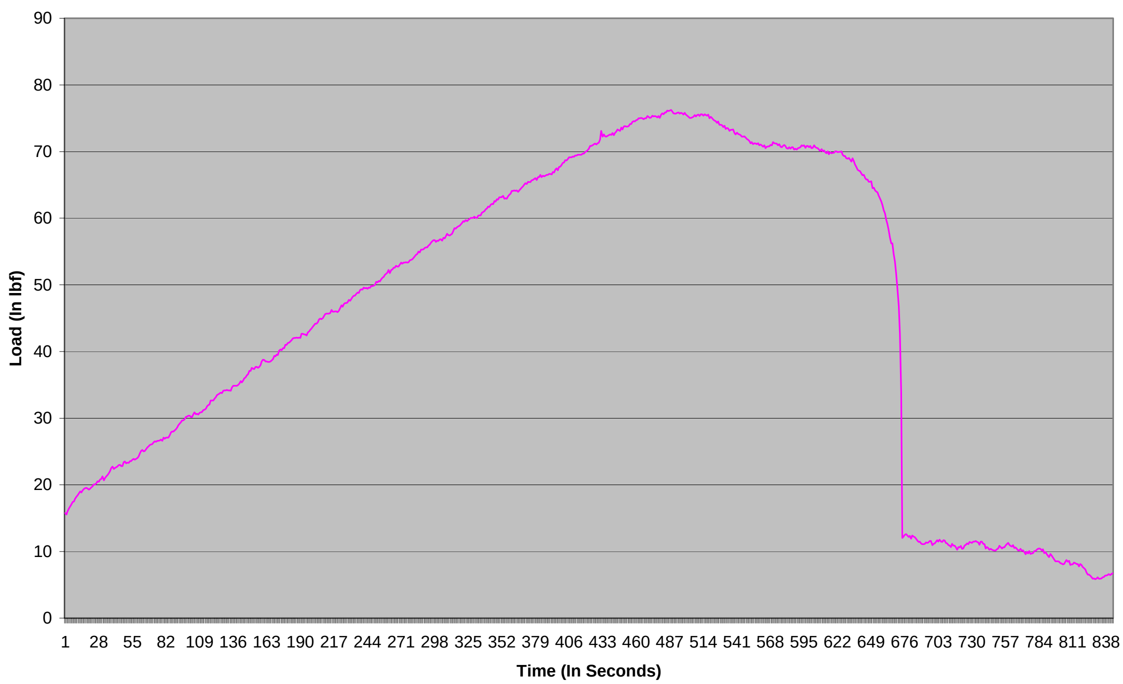

Securos 2-Femur
Load (In lbf)
0
10
20
30
40
50
60
70
80
90
1
44
87
130
173
216
259
302
345
388
431
474
517
560
603
646
689
732
775
818
861
904
947
990
1033
Time (In Seconds)


Securos 2-Tibia
Load (In lbf)
0
5
10
15
20
25
30
1
25
49
73
97
121
145
169
193
217
241
265
289
313
337
361
385
409
433
457
481
505
529
553
577
601
625
649
673
697
721
745
Time (In Seconds)

Securos 3-Femur



Securos 3-Tibia



VITA

Name	Silpa P. Jonnalagadda
Date of Birth	03.19.1979
Permanent Address	12-2-830/5, F-2 Maruthi Apts Hill Colony, Mehdipatnam, Hyderabad, A. P.-500028, India.
Degrees Received/Expected	B.E. Biomedical Engineering Osmania University. M.S. Biomedical Engineering Texas A&M University.